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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,739	09/27/2000	Brian G. Scrivens	P-5015	7708

7590

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Richard J Rodrick Esq  
Becton Dickinson and Company  
1 Becton Drive  
Franklin Lakes, NJ 07417-1880

EXAMINER

COLE, MONIQUE T

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 12/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/670,739

Applicant(s)

SCRIVENS ET AL.

Examiner

Monique T. Cole

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a limitation, namely, channel dimension, which perform the claimed method of increasing cellular or particulate concentration for optical examination. Absent such a limitation, it is unclear that the method, as currently written, would be able to perform its recited function. Upon inspection of the specification (page 3, lines 2-5 and page 5, lines 10-12), it would appear that in order for to obtain increased concentration, there must necessarily be some differential in the sizes of the channel. Further clarification is required.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

or,

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1, 3, 4 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,465,257 to Parce et al. (herein referred to as "Parce").

Parce teaches a microfluidic device and method using the same that comprises directing one or more materials serially introduced into a microscale channel, into a plurality of parallel channels fluidly connected to the microscale channel. The method comprises providing a microfluidic device having at least a first microscale transverse channel, at least first and second microscale side channels intersecting a first side of the transverse channel, at least a third and fourth microscale side channels intersecting a second side of the transverse channel (col. 3, lines 28-36). The device may include an optical detection window disposed across one or more channels and/or chambers of the device. Optical detection windows are typically transparent such that they are capable of transmitting an optical signal from the channel/chamber over which they are disposed. Optical detection windows may merely be a region of a transparent cover layer (co. 6, lines 24-32).

5. Claims 1, 2, 4-8, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,454,945 to Weigl et al. (herein referred to as "Weigl").

Weigl teaches a microfluidic system comprising a plurality of inlets; means for controlling fluid flow through at least one of said inlets connected with said inlet; a laminar flow channel in fluid communication with said inlets; at least three outlets in fluid communication with said laminar flow channel; and means for controlling fluid flow through at least one of said outlets connected with said outlet (col. 7, lines 15-23). Detection and analysis is done by optical means (col. 8, lines 34-35). The input or sample stream may be any stream containing particles of the same or different size, for example blood (col. 9, lines 7-8). In a preferred embodiment, when the sample stream is whole blood, small ions diffuse rapidly across the channel, whereas larger particles diffuse slowly (col. 9, lines 16-24). The inlets need only be sized large enough to conduct the streams of parallel laminar flow (col. 10, lines 50-52). The width and depth of the inlet and outlet channels must be large enough to allow the passage of the undesired particles (col. 10, lines 63-64). In Figure 4, there is exemplified a microchannel configuration having multiple product channels to separate different sized particles.

***Claim Rejections - 35 USC § 103***

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 9-12 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce in view of USP 4,618,476 to Columbus (herein referred to as "Columbus").

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Parce, as applied above, fails to teach a microfluidic device that comprises notches. According to the instant specification, notches serve the purpose of “creating a momentary barrier to progression of the advancing fluid meniscus until the meniscus has contacted the notch across the whole width of the chamber. Eventually the fluid wets into the notch, allowing the fluid to advance into the next notch where the meniscus is again evened out.”

Columbus teaches a capillary transport device (microfluidic device) having speed and meniscus control means that are functionally equivalent to the instantly claimed notches. See Figure 1. The notches are “effective to retard the rate of flow of liquid though the zone (chamber)”. Thus, given the teaching of Columbus, it would have been obvious to one having ordinary skill in the art to modify the microfluidic device of Parce, to include notches for the purpose of more effectively filling the device to allow a more precise filtering of the components therein, thereby creating an increased particulate concentration.

8. Claims 9-12 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weigl in view of Columbus.

Weigl, as applied above, fails to teach a microfluidic device that comprises notches. According to the instant specification, notches serve the purpose of “creating a momentary barrier to progression of the advancing fluid meniscus until the meniscus has contacted the notch across the whole width of the chamber. Eventually the fluid wets into the notch, allowing the fluid to advance into the next notch where the meniscus is again evened out.”

Columbus teaches a capillary transport device (microfluidic device) having speed and meniscus control means that are functionally equivalent to the instantly claimed notches. See Figure 1. The notches are “effective to retard the rate of flow of liquid though the zone

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(chamber)". Thus, given the teaching of Columbus, it would have been obvious to one having ordinary skill in the art to modify the microfluidic device of Weigl, to include notches for the purpose of more effectively filling the device to allow a more precise filtering of the components therein, thereby creating an increased particulate concentration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 703-305-0447. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0661.

Monique T. Cole  
Examiner  
Art Unit 1743

MC *MC*  
December 1, 2002

*Jill Warden*  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700